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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,858	02/18/2005	Sadanobu Shirai	2005_0152A	3564
513 7590 01/04/2007 WENDEROTH, LIND & PONACK, L.L.P. 2033 K STREET N. W. SUITE 800 WASHINGTON, DC 20006-1021			EXAMINER AHMED, HASAN SYED	
			ART UNIT	PAPER NUMBER
			1615	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		01/04/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/524,858

Applicant(s)

SHIRAI ET AL.

Examiner

Hasan S. Ahmed

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 July 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

1. Receipt is acknowledged of applicants' amendment/remarks, which were filed on 13 October 2006.
2. The amendment filed on 13 October 2006 has been entered.
3. The 35 U.S.C. 112(2) rejection is withdrawn in light of the amendment.
4. Currently pending claims 1-3 remain rejected under 35 U.S.C. 103(a).

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Higo, et. al. (U.S. Patent No. 5,866,157).

Higo et. al. teach a percutaneous patch formulation (see col. 2, lines 32-39; Example 5). The disclosed patch is comprised of:

- an adhesive layer on a backing (see col. 6, line 7);
- said adhesive layer comprising:
 - 1-4% (w/w) tulobuterol (see col. 3, lines 39 and 58);
 - 0.01-20% (w/w) C₁₁-C₂₂ fatty acids (see col. 4, line 60 – col. 5, line 32);
 - 15-60% (w/w) rubber (see col. 3, line 64 – col. 4, line 9);

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- 10-70% (w/w) adhesive resin (see col. 4, lines 19 - 37); and
- 10-60% (w/w) plasticizer (see col. 4, lines 38 - 59).

Higo, et. al. explain that combining the disclosed agents into a patch formulation is beneficial because it results in increased percutaneous absorption of active agents and reduced skin irritation (see col. 2, lines 26-29).

While Higo, et. al. do not explicitly teach all the instantly claimed percentages, it is the position of the examiner that it would have been obvious to one of ordinary skill in the art at the time the invention was made to determine suitable percentages through routine or manipulative experimentation to obtain the best possible results, as these are variable parameters attainable within the art.

Moreover, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456; 105 USPQ 233, 235 (CCPA 1955). Applicants have not demonstrated any unexpected or unusual results, which accrue from the instant percentage ranges.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have combined tulobuterol, a rubber, an adhesive resin, a higher fatty acid, and a plasticizer into a patch formulation, as taught by Higo, et. al. Motivation, as explained by Higo, et. al., comes from increased percutaneous absorption of active agents and reduced skin irritation.

* * * * *

Response to Arguments

Applicant's arguments filed on 13 October 2006 have been fully considered but they are not persuasive.

1. Applicants argue that "[t]here is absolutely no suggestion in the Higo et al. reference which would lead one of ordinary skill in the art to use a higher fatty acid such as a C₁₁-C₂₂ fatty acid alone, instead of a combination of an organic acid and absorption enhancer as described in the reference." See remarks, page 6, fourth full-paragraph; emphasis removed.

Examiner respectfully submits that the Higo et al. reference reads on the instant application as claimed. The instant claims are constructed using the transitional phrase "containing." As noted in MPEP 2111.03:

The transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., > Mars Inc. v. H.J. Heinz Co., 377 F.3d 1369, 1376, 71 USPQ2d 1837, 1843 (Fed. Cir. 2004) ("like the term comprising,' the terms containing' and mixture' are open-ended.").

Thus, additional, unrecited elements such as organic acids are not excluded from the instant application, as claimed.

2. Applicants argue that the Higo et al. reference does not suggest that the use of a higher fatty acid alone will "...result in a patch containing tulobuterol in a lower

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concentration having stable release controllability.” See remarks, page 6, fourth full-paragraph.

Again, examiner respectfully submits that the Higo et al. reference reads on the instant application as claimed. None of the instant claims recite “stable release controllability. The instant claims recite, “a drug-release controlling agent.” The latter limitation differs significantly from the former. The scope of the former is much broader than the scope of the latter. As such, examiner respectfully submits that the Higo, et al. reads on the instant application as claimed, since the ingredients disclosed by Higo, et al. inherently act as drug-release controlling agents (*see above*).

* * * * *

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

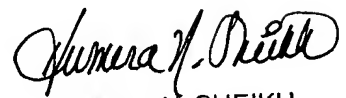
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Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hasan S. Ahmed whose telephone number is 571-272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


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TC-1600